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efm—EFM today  
et—Equal time

ed—Editorial  
nl—News from the literature  
oa—Original article  
pr—Protocol

ppc—Problem-patient  
conference  
s—Symposium  
uc—Ultrasound clinic

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# For cures you can count on **Monistat 7** <sup>Vaginal</sup> Cream TRADEMARK (miconazole nitrate 2%)

**Highly effective...  
low rate of relapse**

**MONISTAT 7 Vaginal Cream** (miconazole nitrate 2%)  
**Description:** MONISTAT 7 Vaginal Cream (miconazole nitrate 2%) is a water-miscible, white cream containing as the active ingredient, 2% miconazole nitrate, 1-[2, 4-dichloro- $\beta$ -(2, 4-dichlorobenzoyloxy) phenethyl] imidazole nitrate.

**Actions:** MONISTAT 7 Vaginal Cream exhibits fungicidal activity *in vitro* against species of the genus *Candida*. The pharmacologic mode of action is unknown.

**Indications:** MONISTAT 7 Vaginal Cream is indicated for the local treatment of vulvovaginal candidiasis (moniliasis). As MONISTAT 7 Vaginal Cream is effective only for candidal vulvovaginitis, the diagnosis should be confirmed by KOH smears and/or cultures. Other pathogens commonly associated with vulvovaginitis (*Trichomonas* and *Haemophilus vaginalis* [*Gardnerella*]) should be ruled out by appropriate laboratory methods.

MONISTAT 7 is effective in both pregnant and non-pregnant women, as well as in women taking oral contraceptives. (See Precautions.)

**Contraindications:** Patients known to be hypersensitive to this drug.

**Precautions:** General: Discontinue drug if sensitization or irritation is reported during use. Laboratory Tests: If there is a lack of response to MONISTAT 7, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens.

**Pregnancy:** Since MONISTAT is absorbed in small amounts from the human vagina, it should be used in the first trimester of pregnancy only when the physician considers it essential to the welfare of the patient.

Clinical studies, during which MONISTAT was used for 14 days, included 209 pregnant patients. Follow-up reports now available in 117 of these patients reveal no adverse effects or complications attributable to MONISTAT therapy in infants born to these women.

**Adverse Reactions:** During clinical studies with MONISTAT for a 14-day regimen, 39 of the 528 patients (7.4%) treated with MONISTAT reported complaints during therapy that were possibly drug-related. Most complaints were reported during the first week of therapy. Vulvovaginal burning, itching or irritation occurred in 6.6%, while other complaints such as vaginal burning, pelvic cramps, hives, skin rash and headache occurred rarely (each less than 0.2% patient incidence). The therapy-related dropout rate was 0.9%.

**Clinical:** Statistical analysis of randomized clinical trials, conducted to determine the shortest effective course of therapy with MONISTAT, demonstrates that a regimen of seven or more days has a cure rate equivalent to the 14-day regimen.

The graphic representation of this conclusion plots days of therapy versus cure rates. The solid line represents the mean therapeutic cure rate and the shaded area represents the 95% confidence interval.

**Dosage and Administration:** One applicatorful is administered intravaginally once daily at bedtime for seven days. Course of therapy may be repeated after other pathogens have been ruled out by appropriate smears and cultures.

**Supplied:** MONISTAT 7 Vaginal Cream is available in 1.66 oz. (47 g) tubes with ORTHO® Measured-Dose Applicator.

®Trademark

ORTHO PHARMACEUTICAL CORPORATION  
Raritan, New Jersey 08869



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## Brief Summary

### CEFOBID® (cefoperazone sodium)

(cefoperazone sodium)

CONTRAINDICATIONS: CEFEBID is contraindicated in patients with known allergy to the cephalosporin-class of antibiotics.

**WARNINGS:** BEFORE THERAPY WITH CEFEBID IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

**PSEUDOMEMBRANOUS COLITIS** HAS BEEN REPORTED WITH THE USE OF CEPHALOSPORINS (AND OTHER BROAD-SPECTRUM ANTIBIOTICS); THEREFORE, IT IS IMPORTANT TO CONSIDER ITS DIAGNOSIS IN PATIENTS WHO DEVELOP DIARRHEA IN ASSOCIATION WITH ANTIBIOTIC USE.

**PRECAUTIONS:** Although transient elevations of the BUN and serum creatinine have been observed, CEFEBID alone does not appear to cause significant nephrotoxicity. However, concomitant administration of aminoglycosides and other cephalosporins has caused nephrotoxicity.

CEFOBID is extensively excreted in bile. The serum half-life of CEFEBID is increased 2-4 fold in patients with hepatic disease and/or biliary obstruction. In general, total daily dosage above 4 g should not be necessary in such patients. If higher dosages are used, serum concentrations should be monitored.

Because renal excretion is not the main route of elimination of CEFEBID (see CLINICAL PHARMACOLOGY), patients with renal failure require no adjustment in dosage when usual doses are administered. When high doses of CEFEBID are used, concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly.

The half-life of CEFEBID is reduced slightly during hemodialysis. Thus, dosing should be scheduled to follow a dialysis period. In patients with both hepatic dysfunction and significant renal disease, CEFEBID dosage should not exceed 1-2 g daily without close monitoring of serum concentrations.

As with other antibiotics, Vitamin K deficiency has occurred rarely in patients treated with CEFEBID. Those at risk include patients with a poor nutritional status, malabsorption states (e.g., cystic fibrosis), alcoholism, and patients on prolonged hyper-alimentation regimens (administered either intravenously or via a naso-gastric tube). Prothrombin time should be monitored in these patients and exogenous Vitamin K administered as indicated.

A disulfiram-like reaction characterized by flushing, sweating, headache, and tachycardia has been reported when alcohol (beer, wine) was ingested within 72 hours after CEFEBID administration. Patients should be cautioned about the ingestion of alcoholic beverages following the administration of CEFEBID. A similar reaction has been reported with other cephalosporins.

Prolonged use of CEFEBID may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. CEFEBID should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

#### Drug Laboratory Test Interactions

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

The maximum duration of CEFEBID animal toxicity studies is six months. In none of the *in vivo* or *in vitro* genetic toxicology studies did CEFEBID show any mutagenic potential at either the chromosomal or subchromosomal level. CEFEBID produced no impairment of fertility and had no effects on general reproductive performance or fetal development when administered subcutaneously at daily doses up to 500 to 1000 mg/kg prior to and during mating, and to pregnant female rats during gestation. These doses are 10 to 20 times the estimated usual single clinical dose.

**Usage in Pregnancy: Pregnancy Category B.** Reproduction studies have been performed in mice, rats, and monkeys at doses up to 10 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to CEFEBID. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Usage in Nursing Mothers:** Only low concentrations of CEFEBID are excreted in human milk. Although CEFEBID passes poorly into breast milk of nursing mothers, caution should be exercised when CEFEBID is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS:** In clinical studies the following adverse effects were observed and were considered to be related to CEFEBID therapy or uncertain etiology:

**Hypersensitivity:** As with all cephalosporins, hypersensitivity manifested by skin reactions (1 patient in 45), drug fever (1 in 260), or a change in Coombs' test (1 in 60) has been reported. These reactions are more likely to occur in patients with a history of allergies, particularly to penicillin.

**Hematology:** As with other beta-lactam antibiotics, reversible neutropenia may occur with prolonged administration. Slight decreases in neutrophil count (1 patient in 50) have been reported. Decreased hemoglobins (1 in 20) or hematocrits (1 in 20) have been reported, which is consistent with published literature on other cephalosporins. Transient eosinophilia has occurred in 1 patient in 10.

**Hepatic:** Of 1285 patients treated with cefoperazone in clinical trials one patient with a history of liver disease developed significantly elevated liver function enzymes during CEFEBID therapy. Clinical signs and symptoms of nonspecific hepatitis accompanied these increases. After CEFEBID therapy was discontinued, the patient's enzymes returned to pre-treatment levels and the symptomatology resolved. As with other antibiotics that achieve high bile levels, mild transient elevations of liver function enzymes have been observed in 5-10% of the patients receiving CEFEBID therapy. The relevance of these findings, which were not accompanied by overt signs or symptoms of hepatic dysfunction, has not been established.

**Gastrointestinal:** Diarrhea or loose stools has been reported in 1 in 30 patients. Most of these experiences have been mild or moderate in severity and self-limiting in nature. In all cases, these symptoms responded to symptomatic therapy or ceased when cefoperazone therapy was stopped. Nausea and vomiting have been reported rarely.

Symptoms of pseudomembranous colitis can appear during or for several weeks subsequent to antibiotic therapy (see WARNINGS).

**Renal Function Tests:** Transient elevations of the BUN (1 in 16) and serum creatinine (1 in 48) have been noted.

**Local Reactions:** CEFEBID is well tolerated following intramuscular administration. Occasionally, transient pain (1 in 140) may follow administration by this route. When CEFEBID is administered by intravenous infusion some patients may develop phlebitis (1 in 120) at the infusion site.

For Intravenous or Intramuscular Use

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ROERIG 

A division of Pfizer Pharmaceuticals  
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# HYPRHO-D

Rh<sub>0</sub> (D) Immune Globulin (Human)

## Summary of Prescribing Information

**DESCRIPTION** Rh<sub>0</sub>(D) Immune Globulin (Human) — Hyprho®-D is a sterile solution of immune globulin containing antibodies to Rh<sub>0</sub>(D) prepared from human venous plasma collected from carefully screened donors. It contains 16.5 ± 1.5% protein stabilized with 0.3 M glycine and preserved with 1.0,000 thimerosal (a mercury derivative). The pH is adjusted with sodium carbonate. Hyprho-D has been tested against the potency found equal to or greater than that of the U.S. Food and Drug Administration Reference Rh<sub>0</sub>(D) Immune Globulin (Human). One vial has been shown to effectively suppress the immunizing potential of 15 ml of Rh<sub>0</sub>(D) positive or D<sup>+</sup> positive packed red blood cells.

This product has been prepared from large pools of human venous plasma. Each individual unit of plasma has been found nonreactive for hepatitis B surface antigen (HBsAg) using a U.S. Federally approved test of at least third-generation sensitivity.

### INDICATIONS AND USAGE

**Pregnancy and Other Obstetric Conditions.**

Hyprho-D is recommended for the prevention of Rh hemolytic disease of the newborn by its administration to the Rh<sub>0</sub>(D) negative, D<sup>-</sup> negative mother within 72 hours after birth of a Rh<sub>0</sub>(D) positive or D<sup>+</sup> positive infant, providing the following criteria are met:

1. The mother must be Rh<sub>0</sub>(D) and D<sup>-</sup> negative and must not already be sensitized to the Rh<sub>0</sub>(D) factor.
2. Her child must be Rh<sub>0</sub>(D) positive or D<sup>+</sup> positive, and should have a negative direct Coombs test. A positive direct Coombs test may be caused by antibodies other than Rh<sub>0</sub>(D) and while this does not contraindicate therapy with Hyprho-D, it should be investigated. A positive direct Coombs test due to anti-Rh<sub>0</sub>(D) is a contraindication to the use of Hyprho-D.

Even though Rh hemolytic disease of the newborn is less frequent when there is ABO incompatibility between the Rh<sub>0</sub>(D) negative mother and the Rh<sub>0</sub>(D) positive fetus, protection against Rh<sub>0</sub>(D) sensitization may be incomplete, and treatment of the mother with Hyprho-D is indicated in such cases.

The administration of Rh<sub>0</sub>(D) Immune Globulin within 72 hours of a full-term delivery of an infant to a Rh<sub>0</sub>(D) negative, D<sup>-</sup> negative mother at risk reduces the incidence of Rh isosensitization from 12-13% to 1-2%. The 1-2% treatment failures are probably due to isosensitization occurring during the latter part of pregnancy or following delivery. Bowman, et al, have reported that the incidence of isosensitization can be further reduced from approximately 1.6% to less than 0.1% by administering Rh<sub>0</sub>(D) Immune Globulin in two doses, one antenatal at 28 weeks gestation and another following delivery.

Hyprho-D should also be administered within 72 hours to all nonimmunized Rh<sub>0</sub>(D) negative, D<sup>-</sup> negative women who have undergone spontaneous or induced abortion, following ruptured tubal pregnancy or following amniocentesis unless the blood type of the fetus is known to be Rh<sub>0</sub> negative, D<sup>-</sup> negative. If the fetal blood type is unknown, one must assume that it is Rh<sub>0</sub>(D) positive and Rh<sub>0</sub>(D) Immune Globulin (Human) — Hyprho®-D should be administered to the mother.

**TRANSFUSION** Hyprho-D may be used to prevent isosensitization in Rh<sub>0</sub>(D) negative, D<sup>-</sup> negative individuals who have been transfused with Rh<sub>0</sub>(D) positive or D<sup>+</sup> positive red blood cells or blood components containing red blood cells.

### CONTRAINDICATIONS

Hyprho-D is contraindicated for use in:

1. A Rh<sub>0</sub>(D) positive or D<sup>+</sup> positive individual.
2. A Rh<sub>0</sub>(D) negative or D<sup>-</sup> negative individual previously sensitized to the Rh<sub>0</sub>(D) or D<sup>+</sup> antigen.

**ADVERSE REACTIONS** Reactions to Rh<sub>0</sub>(D) Immune Globulin (Human) are infrequent in Rh<sub>0</sub>(D) negative, D<sup>-</sup> negative individuals and consist primarily of slight soreness at the site of injection and slight temperature elevation. While sensitization to repeated injections of human immune globulin is extremely rare, it has occurred. Elevated bilirubin levels have been reported in some individuals receiving multiple doses of Rh<sub>0</sub>(D) Immune Globulin (Human) following mismatched transfusions. This is believed to be due to a relatively rapid rate of foreign red cell destruction.

No instances of transmission of hepatitis have been reported from the use of human immune globulin prepared by the fractionation methods employed at Cutter Laboratories, Inc.

### PRECAUTIONS

NEVER ADMINISTER Hyprho-D INTRAVENOUSLY.  
NEVER ADMINISTER TO THE NEONATE.

### WARNINGS

1. Solutions which have been frozen should not be used.
2. Partially used vials must be discarded.

### PRE-ADMINISTRATION LABORATORY PROCEDURES

Using a broad-spectrum compatibility test, i.e., a test capable of detecting so-called "incomplete antibodies," check the individual's serum for Rh<sub>0</sub>(D) antibody to ascertain that the patient has not been already sensitized to the Rh<sub>0</sub>(D) blood factor.

### INJECTION PROCEDURE

#### A. Single Vial Dose

INJECT ENTIRE CONTENTS OF THE VIAL INTO THE INDIVIDUAL INTRAMUSCULARLY. DO NOT INJECT INTRAVENOUSLY. DO NOT INJECT NEONATE.

#### B. Multiple Vial Dose

1. Calculate the number of vials of Hyprho®-D to be given.
2. The total volume of Hyprho-D can be given in divided doses at different sites at one time or the total dose may be divided and injected at intervals provided the total dosage is given within 72 hours of the fetal-maternal hemorrhage or transfusion. Using sterile technique, withdraw the entire contents of the calculated number of vials and inject them intramuscularly into the patient.

## Cutter Biological

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Miles Laboratories, Ltd., Canada

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# Stadol<sup>IM</sup><sub>IV</sub> (butorphanol tartrate)

## the effective analgesic with the safety difference

### Brief Summary of Prescribing Information STADOL® (butorphanol tartrate)

For complete information, consult Official Package Circular.

(2) 12/10/79

**INDICATIONS AND USAGE**—Stadol is recommended for the relief of moderate to severe pain. Stadol can also be used for preoperative or preanesthetic medication, as a supplement to balanced anesthesia, and for the relief of prepartum pain.

**CONTRAINDICATIONS**—Stadol should not be administered to patients who have been shown to be hypersensitive to it.

**WARNINGS**—**Patients Physically Dependent on Narcotics:** Because of its antagonist properties, Stadol is not recommended for patients physically dependent on narcotics. Detoxification in such patients is required prior to use.

Due to the difficulty in assessing addiction in patients who have recently received substantial amounts of narcotic medication, caution should be used in the administration of Stadol. Detoxification of such patients prior to usage should be carefully considered.

**Drug Dependence:** Special care should be exercised in administering Stadol to emotionally unstable patients and to those with a history of drug misuse. When long-term therapy is contemplated, such patients should be closely supervised. Even though Stadol has a low physical dependence liability, care should be taken that individuals who may be prone to drug abuse are closely supervised. It is important to avoid increases in dose and frequency of injections by the patient and to prevent the use of the drug in anticipation of pain rather than for the relief of pain.

**Head Injury and Increased Intracranial Pressure:** Although there is no clinical experience in patients with head injury, it can be assumed that Stadol, like other potent analgesics, elevates cerebrospinal fluid pressure. Therefore the use of Stadol in cases of head injury can produce effects (e.g., miosis) which may obscure the clinical course of patients with head injuries. In such patients Stadol must be used with extreme caution and only if its use is deemed essential.

**Cardiovascular Effects:** Because Stadol increases the work of the heart, especially the pulmonary circuit, the use of this drug in acute myocardial infarction or in cardiac patients with ventricular dysfunction or coronary insufficiency should be limited to those who are hypersensitive to morphine sulfate or meperidine.

**PRECAUTIONS**—**Cardiac Respiratory Conditions:** Because Stadol causes some respiratory depression, it should be administered only with caution and low dosage to patients with respiratory depression (e.g., from other medication, uremia, or severe infection), severely limited respiratory reserve, bronchial asthma, obstructive respiratory conditions, or cyanosis.

**Impaired Renal or Hepatic Function:** Although laboratory tests have not indicated that Stadol causes or increases renal or hepatic impairment, the drug should be administered with caution to patients with such impairment. Extensive liver disease may predispose to greater side effects and greater activity from the usual clinical dose, possibly the result of decreased metabolism of the drug by the liver.

**Biliary Surgery:** Clinical studies have not been done to establish the safety of Stadol administration to patients about to undergo surgery of the biliary tract.

**Usage as a Preoperative or Preanesthetic Medication:** Slight increases in systolic blood pressure may occur, therefore caution should be employed when Stadol is used in the hypertensive patient.

**Usage in Balanced Anesthesia:** The use of pancuronium in combination with Stadol may cause an increase in conjunctival changes.

**Usage in Pregnancy:** The safety of Stadol for use in pregnancy prior to the labor period has not been established; therefore, this drug should be used in pregnant patients only when in the judgment of the physician its use is deemed essential to the welfare of the patient.

Reproduction studies have been performed in rats, mice and rabbits and have revealed no evidence of impaired fertility or harm to the fetus due to Stadol at about 2.5 to 5 times the human dose.

**Usage in Labor and Delivery:** Safety to the mother and fetus following administration of Stadol during labor has been established. Patients receiving Stadol during labor have experienced no adverse effects other than those observed with commonly used analgesics. Stadol should be used with caution in women delivering premature infants.

**Usage in Nursing Mothers:** The use of Stadol in lactating mothers who are nursing their infants is not recommended since it is not known whether this drug is excreted in human milk. Stadol has been used safely for labor pain in mothers who subsequently nursed their infants.

**Usage in Children:** Safety and efficacy in children below age 18 years have not been established.

**ADVERSE REACTIONS**—The most frequent adverse reactions in 1250 patients treated with Stadol are: sedation (50.3, 40%), nausea (82, 6%), clammy/sweating (76, 6%). Less frequent reactions are: headache (35, 3%), vertigo (33, 3%), floating feeling (33, 3%), dizziness (23, 2%), lethargy (19, 2%), confusion (15, 1%), lightheadedness (12, 1%). Other adverse reactions which may occur (reported incidence of less than 1%) are:

**CNS:** nervousness, unusual dreams, agitation, euphoria, hallucinations

**Autonomic:** flushing and warmth, dry mouth, sensitivity to cold

**Cardiovascular:** palpitation, increase or decrease of blood pressure

**Gastrointestinal:** vomiting

**Respiratory:** slowing of respiration, shallow breathing

**Dermatologic:** rash or hives

**Eye:** diplopia or blurred vision

**OVERDOSAGE**—**Manifestations:** Although there have been no experiences of overdosage with Stadol during clinical trials, this may occur due to accidental or intentional misuse as well as therapeutic use. Based on the pharmacology of Stadol, overdosage could produce some degree of respiratory depression and variable cardiovascular and central nervous system effects.

**Treatment:** The immediate treatment of suspected Stadol overdosage is intravenous naloxone. The respiratory and cardiac status of the patient should be evaluated constantly and appropriate supportive measures instituted, such as oxygen, intravenous fluids, vasopressors and assisted or controlled respiration.

**NOW SUPPLY**—Stadol (butorphanol tartrate) Injection for I.M. or I.V. use, is available as follows:

NDC 0015-5844-20—2 mg per ml, 2-ml vial

NDC 0015-5845-20—1 mg per ml, 1-ml vial

NDC 0015-5846-20—2 mg per ml, 1-ml vial

NDC 0015-5848-23—2 mg per ml, 1-ml Disposable Syringe

NDC 0015-5848-20—2 mg per ml, 10-ml multi-dose vial

**BRISTOL**

Bristol Laboratories  
Division of Bristol-Myers Company  
Syracuse, New York 13201

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**Brief Summary**  
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**Oral and Intravenous**

**CONTRAINDICATIONS:** Hypersensitivity to any tetracycline.

**WARNINGS:** In the presence of renal dysfunction, intravenous use, particularly in pregnancy, in daily doses exceeding 2 grams has been associated with deaths through liver failure. When need for intensive treatment outweighs potential dangers, perform renal and liver function tests before and during therapy; also follow serum concentrations. In renal impairment, usual doses may lead to excessive accumulation and liver toxicity. Under such conditions, use lower total doses, and, in prolonged therapy, determine serum levels. This hazard is of particular importance in parenteral use in pregnant or postpartum patients with pyelonephritis. In such cases, the blood level should not exceed 15 mcgm/ml and liver function tests should be made at frequent intervals. Do not prescribe other potentially hepatotoxic drugs concomitantly. THE USE OF TETRACYCLINES DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY AND CHILDHOOD TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN). This is more common during long-term use but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported.

**TETRACYCLINES, THEREFORE, SHOULD NOT BE USED IN THIS AGE GROUP UNLESS OTHER DRUGS ARE NOT LIKELY TO BE EFFECTIVE OR ARE CONTRAINDICATED.** Photosensitivity, manifested by an exaggerated sunburn reaction, has been observed in some individuals taking tetracyclines. Advise patients apt to be exposed to direct sunlight or ultraviolet light that such reaction can occur, and discontinue treatment at first evidence of skin erythema. Studies to date indicate that photosensitivity is rarely reported with MINOCIN minocycline HCl. The antianabolic action of tetracycline may cause an increase in BUN. In patients with significantly impaired renal function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia and acidosis. CNS side effects (light-headedness, dizziness, vertigo) have been reported, may disappear during therapy, and always disappear rapidly when drug is discontinued. Caution patients who experience these symptoms about driving vehicles or using hazardous machinery while taking this drug. **Pregnancy:** In animal studies, tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Embryotoxicity has been noted in animals treated early in pregnancy. **Newborns, infants and children:** All tetracyclines form a stable calcium complex in any bone-forming tissue. Prematures, given oral doses of 25 mg/kg every 6 hours, demonstrated a decrease in fibula growth rate, reversible when drug was discontinued. Tetracyclines are present in the milk of lactating women who are taking a drug of this class.

**PRECAUTIONS:** Use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue and institute appropriate therapy. In venereal diseases, when coexistent syphilis is suspected, darkfield examination should be done before treatment is started and blood serology repeated monthly for at least four months. Patients on anticoagulant therapy may require downward adjustment of such anticoagulant dosage. Test for organ system dysfunction (e.g., renal, hepatic and hematopoietic) in long-term use. Treat all Group A beta-hemolytic streptococcal infections for at least 10 days. Avoid giving tetracycline in conjunction with penicillin.

**ADVERSE REACTIONS:** GI: (with both oral and parenteral use): anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, inflammatory lesions (with monilial overgrowth) in anogenital region. **Skin:** maculopapular and erythematous rashes. Exfoliative dermatitis (uncommon). Photosensitivity is discussed above ("Warnings"). Pigmentation of the skin and mucous membranes has been reported. **Renal toxicity:** rise in BUN, dose-related (see "Warnings"). **Hypersensitivity reactions:** urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus. In young infants, bulging fontanels have been reported following full therapeutic dosage, disappearing rapidly when drug was discontinued. **Blood:** hemolytic anemia, thrombocytopenia, neutropenia, eosinophilia. **CNS:** (see "Warnings"). When given over prolonged periods, tetracyclines may produce brown-black microscopic discoloration of thyroid glands; no abnormalities of thyroid function studies are known to occur.

**NOTE:** Rapid administration is to be avoided. Parenteral therapy is indicated only when oral therapy is not adequate or tolerated. Oral therapy should be instituted as soon as possible. If intravenous therapy is given over prolonged periods of time, thrombophlebitis may result.

**CONCOMITANT THERAPY:** Antacids containing aluminum, calcium, or magnesium impair absorption; do not give to patients taking oral minocycline. Studies to date indicate that absorption of MINOCIN is not notably influenced by foods and dairy products. 962-3

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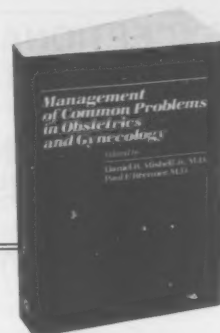
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